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14. ABSTRACT Training specific surgical skills on simulators has been proven to bring a better-prepared student to a human operating room, and when the simulator-trained student performs a portion of a procedure fewer errors are made when compared to a learner who has not been trained on a simulator. This current study seeks to further this work by first developing a curriculum for training an entire procedure, laparoscopic cholecystectomy, using simulation technologies and integrating cognitive, psychomotor aspects of full procedure training, and second, to test the effectiveness of curriculum-based training through a multicenter, international research group, the MASTER group.					
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Introduction

Training specific surgical skills on simulators has been proven to bring a better-prepared student to human operating room, and when the simulator-trained student performs a portion of a procedure fewer errors are made when compared to a learner who has not been trained on a simulator. This current study seeks to further this work by first developing a curriculum for training an entire procedure, laparoscopic cholecystectomy, using simulation technologies and integrating cognitive, psychomotor aspects of full procedure training, and second, to test the effectiveness of curriculum-based training through a multicenter, international research group, the MASTER group.

Body

Thus far the laparoscopic cholecystectomy curriculum including the cognitive and psychomotor components has been developed and validated locally (See Appendix A). Expert performance levels have been established through three separate surveys of advanced laparoscopic surgeons. The first survey was conducted during the 2003 Annual Meeting of the Society of Laparoscopic Surgeons (SLS) where 100 surgeons who had performed in excess of 100 advanced laparoscopic procedures were tested on the MIST-VR. The second occurred during the 2003 Clinical Congress and used the same methodology, and the third during the 2004 Annual SAGES meeting. Results from these surveys have been published and these data are now part of a database for use in setting benchmarks for performance on the MIST-VR (Appendix B & C).

The methodology for executing the study at multiple sites has been developed and distributed (Appendix D). This “cookbook” serves as a step-by-step guide for setting the MIST-VR and establishing local expert levels for collaborating institutions.

Local IRB and DOD HSRRB approval has been acquired at the lead center and other sites are in the process of submitting their local IRBs.

Results from the lead center have shown overall reduction in both time and errors with curriculum- trained group.

Several problems have slowed progress with this project:

1. Technical challenges have become apparent during this time and issues with the durability of simulators has emerged. The MIST is not well supported by industry and there is a need to change the simulation platform to a better and more durable simulator.
2. Programmatic challenges have also hindered this project. Time required to complete DOD HSRRB application and to receive approval from same far exceeded original expectations. Institutional IRB approval has been problematic due to confusion regarding education research. In most cases, education research is except from full IRB review. In this project, the research subjects are students, not patients. When the student is in the operating room and their performance is being videotaped, the attending surgeon is always present and supervises the student at all times. If the student's performance of the operation falls below what would be acceptable for the patient, the attending surgeon takes over the conduct of the operation. This is the standard of care today in all centers with surgical trainees. This take over by the attending is actually a data point which is recorded when the videotaped procedure is scored by blinded reviewers. IRB committees have found this methodology confusing thinking that patients were being exposed to untrained surgeons without oversight. Considerable time was required to educate IRBs on this experimental design.
3. Turnover with collaborating surgeons moving from one academic center to another has meant that some of the original collaborating centers no longer have the skill and leadership to participate in this research. This meant that new centers had to be recruited.
4. The experimental psychologist for this study has left the study (and the country) and is no longer involved.
5. Mentice AB, the company who sells and services MIST-VR has stopped servicing the device and with this, the existing units needed for this research are no longer in service.

Key Research Accomplishments

1. Designed curriculum including cognitive and psychomotor components
2. Validated curriculum and presented results at national meeting
3. Established expert performance levels and published / presented results
4. Secured IRB and HSRRB approval at lead center
5. Distributed execution methodology to collaborating sites
6. ACS presentation on preliminary, single site results
7. Methodology being used by ABS and others in curriculum design
8. Results from lead center

Reportable Outcomes

Manuscripts

1. Gallagher, A. G., C. D. Smith, et al. (2003). "Psychomotor skills assessment in practicing surgeons experienced in performing advanced laparoscopic procedures." Journal of the American College of Surgeons **197**(3): 479-88.
2. Gallagher, A. G., A. B. Lederman, et al. (2004). "Discriminative validity of the Minimally Invasive Surgical Trainer in Virtual Reality (MIST-VR) using criteria levels based on expert performance." Surgical Endoscopy **18**(4): 660-5.

Abstracts

1. McClusky, D. M., C. D. Smith, et al. (2004). Virtual Reality Training Improves Operating Room Performance of PGY 1 & 2 Surgical Residents: Results of a Prospective, Randomized, Double-Blinded Study of the Complete Laparoscopic Cholecystectomy. Proceedings of the Surgical Forum, 2004.
2. Van Sickle, K. R., C. D. Smith, et al. (2005). Setting National Benchmark Proficiency Levels for Laparoscopic Performance Using Simulation: The Results from the 2004 SAGES MIST-VR Learning Center Study. SAGES 2005 Annual Meeting, Accepted for Oral Presentation.

Presentations

1. Virtual Reality Training Improves Operating Room Performance of PGY 1 & 2 Surgical Residents: Results of a Prospective, Randomized, Double-Blinded Study of the Complete Laparoscopic Cholecystectomy. American College of Surgeons Surgical Forum, New Orleans, LA, October 13, 2004.

Conclusions

The research is complete with results from the effort published as detailed above. No further work is possible as noted above. The full procedure curriculum has been developed and validated. Lead center local IRB approval has been secured. New collaborating centers are being recruited. It is anticipated that the 24 study subjects will be enrolled and studies completed in the next 6-9 months. Completion of this work will have significant impact in several ways:

1. This is the first study to validate the benefit and role of simulation for full procedure training,
2. With the focus on curriculum, and not just a specific surgical skill, this work has catalyzed simulation developers to progress past developing technologies that simply train a psychomotor skill, but rather, offerings that incorporate cognitive and psychomotor skills within a curriculum that when integrated into the simulators will provide a package more appealing to the surgical and procedural educators.

References

1. Gallagher, A. G., C. D. Smith, et al. (2003). "Psychomotor skills assessment in practicing surgeons experienced in performing advanced laparoscopic procedures." Journal of the American College of Surgeons **197**(3): 479-88.
2. Gallagher, A. G., A. B. Lederman, et al. (2004). "Discriminative validity of the Minimally Invasive Surgical Trainer in Virtual Reality (MIST-VR) using criteria levels based on expert performance." Surgical Endoscopy **18**(4): 660-5.